Kensey Nash

AUG 15 2005

K043259

510(k) Summary

Submitted by:	Kensey Nash Corporation 55 East Uwchlan Avenue Exton, PA 19341
Contact Person:	Deborah A. Racioppi, RA Compliance Manager Ph: 610-594-4389 Fax: 610-524-0265
Date Prepared:	November 23, 2004
510(k) #:	
Device:	
Trade Name:	BioBlanket™ Surgical Mesh
Common/Usual Name:	Surgical Mesh, Tissue Repair Biomaterial
Proposed Classification:	Surgical Mesh 21 CFR Part 878.3300 (79 FTM) Class II

Device Description:
BioBlanket™ Surgical Mesh is comprised of a single layer porous, cross-linked collagen patch that is supplied sterile and for one-time use.

Intended Use:
BioBlanket™ Surgical Mesh is indicated for use in general surgical procedures for the reinforcement and repair of soft tissue where weakness exists including, but not limited to defects of the thoracic wall, muscle flap reinforcement, rectal and vaginal prolapse, reconstruction of the pelvic floor, hernias, suture line reinforcement and reconstructive procedures. The device is also intended for reinforcement of the soft tissues which are repaired by suture or suture anchors, limited to the supraspinatus, during rotator cuff repair surgery. The device is intended for one time use.

Substantial Equivalence:
In terms of Section 510(k) substantial equivalence, BioBlanket™ Surgical Mesh is similar to the predicate collagen-based surgical mesh devices listed below previously cleared for commercial distribution. The BioBlanket™ Surgical Mesh is substantially equivalent in terms of intended use, technological characteristics, performance and material.

Manufacturer	Device	510(k)	ProCode
Kensey Nash Corp.	BioBlanket™ Surgical Mesh	K041923	FTM
Organogenesis, Inc.	FortaFlex™ Surgical Mesh	K020049	FTM
DePuy, Inc.	Restore® Orthobiologic Soft Tissue Implant	K031969	FTM

Performance Data:
BioBlanket™ Surgical Mesh was subjected to biocompatibility, integrity, in-vitro and in-vivo performance tests. The device passed the requirements of all tests.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 15 2005

Ms. Deborah Racioppi
Regulatory Affairs Compliance Manager, RAC
Kensey Nash Corporation
55 East Uwchlan Avenue
Exton, Pennsylvania 19341

Re: K043259
Trade/Device Name: BioBlanket™ Surgical Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: FTM
Dated: June 30, 2005
Received: July 1, 2005

Dear Ms. Racioppi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use Statement

510(k) Number (if known): K043259

Device Name: BioBlanket™ Surgical Mesh

Indications for Use:

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Prescription Use ___X___ OR Over-the-Counter Use_____
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buehrle for Mark Melkerson

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K043259